

NIST HANDBOOK 150-23
2007 Edition (DRAFT)

**National
Voluntary
Laboratory
Accreditation
Program**

**HOMELAND SECURITY
APPLICATIONS:
RADIATION DETECTION
INSTRUMENTS**

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February 2007



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Foreword

The National Institute of Standards and Technology (NIST) Handbook 150 publication series sets forth the procedures, requirements, and guidance for the accreditation of testing and calibration laboratories by the National Voluntary Laboratory Accreditation Program (NVLAP). The series is comprised of the following publications:

- NIST Handbook 150, *NVLAP Procedures and General Requirements*, which contains the general procedures and requirements under which NVLAP operates as an unbiased third-party accreditation body;
- NIST Handbook 150-xx program-specific handbooks, which supplement NIST Handbook 150 by providing additional requirements, guidance, and interpretive information applicable to specific NVLAP laboratory accreditation programs (LAPs).

The program-specific handbooks are not standalone documents, but rather are companion documents to NIST Handbook 150. Each program-specific handbook tailors the general criteria found in NIST Handbook 150 to the specific test methods, calibrations, or types of tests or calibrations covered by a LAP.

NIST Handbook 150-23, *NVLAP Homeland Security Application – Radiation Detection Instruments*, presents the technical requirements and guidance for the accreditation of laboratories that test radiation detection instruments used in homeland security applications. The 2007 edition of NIST Handbook 150-23 is the first edition of the handbook.

The handbook was written with the participation of technical experts in the field of ionizing radiation detection instrumentation and was approved by NVLAP. The body of the handbook has been structured to conform with internationally accepted rules for the structure and drafting of standards, where appropriate, to promote ease of use and understanding.

This handbook is also available on the NVLAP web site (<http://www.nist.gov/nvlap>).

Questions or comments concerning this handbook should be submitted to NVLAP, National Institute of Standards and Technology, 100 Bureau Drive, Stop 2140, Gaithersburg, MD 20899-2140, phone: 301-975-4016; fax : 301-926-2884; e-mail: nvlap@nist.gov.

Introduction

The laboratory accreditation program for Radiation Detection Instruments used in Homeland Security Applications was established in 2006 in response to a request from the United States Department of Homeland Security (DHS), Science and Technology Directorate. The purpose of the laboratory accreditation program for NVLAP Radiation Detection Instruments – Homeland Security Applications is to recognize competent radiation detection instrument testing laboratories and to improve the quality of radiation detection instruments used by first responders and the federal government by providing periodic evaluations of each laboratory, including an assessment of the laboratory's management system. The testing program is divided into two broad instrument categories as follows: (1) portable/handheld instruments including those worn by first responders, and (2) portal monitors for screening of personnel, packages, rail vehicles, and vehicle/cargo containers. Within this division the radiation detection instruments will either be tested for detection and/or radionuclide identification capabilities.

The radiation detection instrument testing standards used in Homeland Security applications were developed by the Institute of Electrical and Electronic Engineers (IEEE) which is an American National Standards Institute (ANSI) accredited standards developer. The laboratories must follow the current versions (unless noted by a NVLAP laboratory bulletin) of applicable standards such as ANSI/IEEE N42.32, *Performance Criteria for Alarming Personal Radiation Detectors for Homeland Security*, ANSI/IEEE N42.33, *American National Standard for Portable Radiation Detection Instrumentation for Homeland Security*, ANSI/IEEE N42.34, *Performance Criteria for Hand-held Instruments for the Detection and Identification of Radionuclides*, ANSI/IEEE N42.35, *American National Standard for Evaluation and Performance of Radiation Detection Portal Monitors for Use in Homeland Security*, ANSI/IEEE N42.38, *American National Standard for Evaluation and Performance of Spectroscopic Radiation Detection Portal Monitors for Use in Homeland Security*, ANSI/IEEE N42.43, *Performance Criteria for Mobile/Transportable Radiation Monitors used for Homeland Security* and their corresponding Test and Evaluation (T&E) Protocols, such as T&E Protocol N42.32, T&E Protocol N42.33, T&E Protocol N42.34, and T&E Protocol N42.35.

Accreditation is available to any laboratory that tests radiation detection instrument in accordance with standards for these detectors, such as ANSI/IEEE N42.32, N42.33, N42.34, N42.35, N42.38, and N42.43, their corresponding test and evaluation protocols, and this handbook. A foreign-based laboratory may also be accredited by NVLAP if the laboratory meets the same requirements as domestic laboratories and pays any required additional fees.

To be granted accreditation, a laboratory shall satisfy the NVLAP requirements contained in NIST Handbook 150 and this handbook, and shall demonstrate proficiency in the testing of radiation detection instrumentation used in homeland security applications.

NVLAP accreditation does not imply any guarantee (certification) of laboratory performance or test/calibration data. NVLAP accreditation does not imply product certification. NVLAP accreditation is solely a finding of laboratory competence.

1 General information

1.1 Scope

1.1.1 NIST Handbook 150-23 specifies the technical requirements and provides guidance for NVLAP accreditation of laboratories that test radiation detection instruments for use in homeland security applications. This handbook supplements the NVLAP procedures and general requirements found in NIST Handbook 150.

1.1.2 This handbook, NIST Handbook 150, and the NIST Handbook 150 Checklist constitute the collective body of requirements that must be met by a laboratory seeking accreditation in the Radiation Detection Instruments Laboratory Accreditation Program (LAP).

1.1.3 This handbook is intended for information and use by accredited radiation detection instrument testing laboratories, assessors conducting on-site assessments, laboratories seeking accreditation, other laboratory accreditation systems, users of laboratory services, and others needing information on the requirements for NVLAP accreditation under the Radiation Detection Instruments LAP.

1.1.4 The requirements of NIST Handbook 150, the interpretations and specific requirements in this handbook, and the requirements of the test standards for which the laboratory seeks accreditation (e.g., ANSI/IEEE N42.32, N42.33, N42.34, N42.35, N42.38, and N42.43 and their corresponding test and evaluation protocols, etc.) must be combined to produce the criteria for accreditation in the Radiation Detection Instruments LAP.

1.2 Organization of handbook

The numbering and titles of the first five clauses of this handbook match those of NIST Handbook 150. The primary subclauses in clauses 4 and 5 (e.g., 4.1, 4.2, etc.) are also numbered and titled to correspond with those of NIST Handbook 150, even when there are no requirements additional to those in NIST Handbook 150.

1.3 Program description

1.3.1 This accreditation program is designed to satisfy the requirements of contractors, state and local governments, and federal agencies specifying accreditation for laboratories that conduct type testing of radiation detection instruments used in homeland security applications.

1.3.2 Accreditation is available to any organization that conducts type testing of radiation detection instruments used in homeland security applications in accordance with this handbook and corresponding standards referenced as part of the criteria for accreditation.

1.3.3 Laboratories that test radiation detection instruments shall clearly communicate the scope of the laboratory's accreditation.

1.3.4 NVLAP does not prohibit a laboratory from providing additional tests outside the scope of its accreditation, but those tests shall be clearly identified in client reports as not being in the scope of the laboratory's NVLAP accreditation.

1.4 References

The following documents are referenced in this handbook. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) shall apply within one year of publication or within another time limit specified by regulations or other requirement documents.

- NIST Handbook 150, *NVLAP Procedures and General Requirements*
- ANSI/IEEE N42.22, *American National Standard – Traceability of Radioactive Sources to the National Institute of Standards and Technology (NIST) and Associated Instrument Quality Control*
- ANSI/IEEE N42.23, *American National Standard Measurement and Associated Instrumentation Quality Assurance for Radioassay Laboratories*
- ANSI/IEEE N42.32, *Performance Criteria for Alarming Personal Radiation Detectors for Homeland Security*
- ANSI/IEEE N42.33, *American National Standard for Portable Radiation Detection Instrumentation for Homeland Security*
- ANSI/IEEE N42.34, *Performance Criteria for Hand-held Instruments for the Detection and Identification of Radionuclides*
- ANSI/IEEE N42.35, *American National Standard for Evaluation and Performance of Radiation Detection Portal Monitors for Use in Homeland Security*
- ANSI/IEEE N42.38, *American National Standard for Evaluation and Performance of Spectroscopic Radiation Detection Portal Monitors for Use in Homeland Security*
- ANSI/IEEE N42.42, *Data Format Standard for Radiation Detectors used for Homeland Security*
- ANSI/IEEE N42.43, *Performance Criteria for Mobile/Transportable Radiation Monitors used for Homeland Security*
- IEEE Standard 1012, *IEEE Standard for Software Verification and Validation*
- T&E Protocol N42.32, *Testing and Evaluation Protocol for Alarming Personal Radiation Detectors for Homeland Security*
- T&E Protocol N42.33, *Testing and Evaluation Protocol for Portable Radiation Detection Instrumentation for Homeland Security*
- T&E Protocol N42.34, *Testing and Evaluation Protocol for Hand-held Instruments for the Detection and Identification of Radionuclides*
- T&E Protocol N42.35, *Testing and Evaluation Protocol for Evaluation and Performance of Radiation Detection Portal Monitors for Use in Homeland Security*

1.5 Terms and definitions

For the purposes of this handbook, the terms and definitions given in NIST Handbook 150 and ANSI/IEEE N42.32, N42.33, N42.34, N42.35, N42.38, and N42.43, and the following apply.

1.5.1

calibration

A set of operations under specified conditions that establishes the relationship between values indicated by a measuring instrument or measuring system, and the conventionally true values of the quantity or variable being measured.

1.5.2

detector

A device or component designed to produce a quantifiable response to ionizing radiation normally measured electronically.

1.5.3

instrument

A complete system consisting of one or more assemblies designed to quantify one or more characteristics of ionizing radiation or radioactive material.

1.5.4

test

A procedure whereby an instrument, circuit, or component is evaluated.

1.5.5

type test

Initial test of instruments representative of production made to a specific design to show that the design meets defined specifications.

1.5.6

validation test

Evaluation or measurement of performance characteristics of the laboratory's equipment to verify that certain stated specifications and contractual requirements are met.

1.6 Program documentation

1.6.1 General

NVLAP checklists enable assessors to document the assessment of a laboratory against the NVLAP requirements found in NIST Handbook 150, this handbook, and in some cases, the checklists themselves. Checklists contain definitive statements or questions about all aspects of the NVLAP criteria for accreditation, and form part of the On-Site Assessment Report (see NIST Handbook 150). Use of checklists helps to ensure the completeness, objectivity, and uniformity of the on-site assessment process.

1.6.2 NIST Handbook 150 Checklist

All NVLAP programs use the NIST Handbook 150 Checklist, which contains the requirements published in NIST Handbook 150. The checklist items are numbered to correspond to clauses 4 and 5 and annexes A and B of NIST Handbook 150. The current version of this checklist is available from the NVLAP web site at <<http://www.nist.gov/nvlap>>.

1.6.3 NIST Handbook 150-23 Checklist

The NIST Handbook 150-23 Checklist addresses the requirements specific to the Homeland Security Applications – Radiation Detection Instruments LAP. The checklist items are numbered to correspond to clauses 4 and 5 of NIST Handbook 150-23. The current version of this checklist is available from the NVLAP web site at <<http://www.nist.gov/nvlap>>.

1.6.4 NVLAP Lab Bulletins

NVLAP Lab Bulletins are issued to laboratories and assessors, when needed, to clarify program-specific requirements and to provide information about program additions and changes.

2 LAP establishment, development and implementation

This clause contains no information additional to that provided in NIST Handbook 150, clause 2.

3 Accreditation process

3.1 General

3.1.1 This clause discusses the assessment and accreditation process for laboratories in the LAP for Homeland Security Applications – Radiation Detection Instruments.

3.1.2 An overview of the laboratory accreditation process is provided in NIST Handbook 150, clause 3, and includes information pertaining to application for accreditation; on-site assessment; proficiency testing; accreditation decision; granting accreditation; renewal of accreditation; changes to scope of accreditation; monitoring visits; and suspension, denial, revocation, and voluntary termination of accreditation.

3.1.3 The assessment process consists of a NVLAP review of the application and laboratory management system documentation, an on-site assessment visit, and proficiency testing.

3.1.4 NVLAP management may consider a preassessment on-site visit to better define the laboratory's requested scope of accreditation. In such cases, the preassessment costs will be charged to the laboratory in addition to the actual On-Site Assessment Fee.

3.2 Management system review

3.2.1 When NVLAP headquarters receives the application, management system documents, and required procedures, one or more NVLAP assessors are assigned to review the management system documentation, which includes the laboratory's quality manual. The assigned assessors will review the documents to ensure they cover all aspects of the management system related to quality and, if followed, satisfy the requirements in NIST Handbook 150-23, NIST Handbook 150 (including Annex A and Annex B), and the requirements of the test standards (i.e., ANSI/IEEE N42.32, N42.33, N42.34, N42.35, N42.38, N42.43, etc.) for which the laboratory seeks accreditation. Prior to conducting the on-site assessment, the NVLAP assessor(s) may request a copy of the laboratory's quality manual and cross-reference documentation that verifies that all the requirements of NIST Handbook 150 are addressed in the management system documentation.

3.2.2 During the review, the NVLAP assessor may identify nonconformities and require changes to the management system so that it meets the requirements. A NVLAP assessor may ask for additional management system documents related to quality.

3.3 On-site assessment

3.3.1 When the management system review has been completed and nonconformities resolved, NVLAP schedules the on-site assessment.

3.3.2 The assessment will take place at the laboratory site. The NVLAP assessor typically conducts the on-site assessment over a three-day time period. The assessment time may be longer depending on the number of radiation detection instrument types and test categories for which a laboratory is accredited. Efforts will be made to minimize disruption to the normal working routines during the assessment. The NVLAP assessor will need time and workspace to complete assessment documentation during his/her time at the laboratory site.

3.3.3 The laboratory shall have its facilities and equipment in good working order and be ready for examination according to the requirements identified in this handbook, NIST Handbook 150, and the laboratory's quality manual.

3.3.4 The laboratory shall make available, at the beginning of the on-site assessment, all supporting technical information in a format that is conducive to a detailed review.

3.3.5 NVLAP assessors will use the NIST Handbook 150 Checklist and the NIST Handbook 150-23 Checklist. The checklists and the technical specifics contained in this handbook ensure that the assessment is complete and that all assessors cover the same items at each laboratory.

3.3.6 The activities covered during a typical on-site assessment are described below. A NVLAP assessor, prior to the visit, shall provide a preliminary agenda, which may change due to findings observed during the on-site assessment.

- a) *Opening meeting:* The NVLAP assessor(s) will meet with laboratory management and supervisory personnel, and other personnel at the discretion of the laboratory's management to explain the purpose of the on-site assessment and to discuss the schedule for the assessment activities. Information provided by the laboratory on its application form may be discussed during this meeting.

- b) *Staff interviews:* The NVLAP assessor will ask the laboratory manager to assist in arranging times for individual interviews with laboratory staff members. The assessor will interview staff members filling key positions (e.g., Laboratory Manager, Technical Director, Quality Manager, Authorized Representative) and staff members who have an effect on the outcome of the testing. The assessor does not need to talk to all staff members; however, the assessor will select staff members representing all aspects of the laboratory. These interviews are conducted to determine if the staff members are properly trained, assigned, and supervised, and are technically competent for the tasks assigned to them.
- c) *Records review:* The NVLAP assessor will review laboratory documentation, including the management system, quality manual, equipment and maintenance records, record-keeping procedures, testing procedures, laboratory test records and reports, personnel competency records, personnel training plans and records, and safeguards for the protection of sensitive and proprietary information. The assessor may request additional information in an effort to clarify issues regarding nonconformity or to delve more deeply into a technical issue.

Laboratory staff shall be available to answer questions; however, the NVLAP assessor may wish to review the documents and records alone. The assessor usually does not ask to remove any laboratory documents or records from the laboratory premises.

NVLAP assessors do not need access to information that may be considered sensitive or private such as salary, medical information, or performance reviews for work done outside the scope of the laboratory's accreditation. However, this information is often stored together with technical information that an assessor will need to check (e.g., job descriptions, resumes, and technical performance reviews). In these cases, the assessor will work with the laboratory to ensure the review is performed without violating individual privacy. At the discretion of the laboratory, a member of the human resources department may be present during the review of personnel information.

- d) *Internal audit and management review:* The NVLAP assessor will review and discuss with the laboratory staff the laboratory's internal audit and management review activities, which are separate and distinct activities. The discussion will include all aspects of those activities including the quality system procedures, the audit findings, the results of the management review, and the actions taken to resolve problems identified.
- e) *Equipment and software:* The NVLAP assessor will examine the suitability of all equipment and facilities required to perform the standard test methods for which the laboratory is accredited (or is seeking accreditation). The assessor will examine radiological type testing equipment including required validation tests, test sources, environmental chambers, calibration ranges and associated computer hardware and software for function and compliance with this handbook and all associated standards. The assessor will also review any associated software validations and verification procedures used as part of the testing and the data report formatting. All equipment required to conduct radiological type testing shall be available for review.
- f) *Demonstrations:* The demonstrations requested may be selective or all-inclusive. The NVLAP assessor will observe selected or all-inclusive radiation detection type testing of instruments in different classes as they apply to the ANSI/IEEE N42 series of standards and discuss them with the technical personnel to assure their understanding of the procedures. The assessor may select and trace the history of one or more instruments from receipt to final issuance of the test results.

- g) *Proficiency testing:* The NVLAP assessor will discuss all aspects of proficiency testing results with appropriate staff. Test methodology and records documenting the laboratory's execution of the testing will be reviewed and discussed. Unusual trends and outlying results will be discussed.
- h) *On-site assessment report:* The NVLAP assessor will complete an on-site assessment report, which summarizes the findings. This report normally consists of the On-Site Report, the NIST Handbook 150 Checklist, and the NIST Handbook 150-23 Checklist. The first page of the report is signed by the NVLAP assessor and the laboratory's Authorized Representative. The assessor will give a copy of the report to the laboratory representative for retention and send the original report to NVLAP.
- i) *Closing meeting:* The NVLAP assessor will conduct a closing meeting with the laboratory management, supervisory personnel, and other staff members at the discretion of the laboratory's management to discuss findings. During the visit the assessor will have categorized all problems identified as nonconformities and comments. They will be discussed at the closing meeting and resolutions may be mutually agreed upon. The assessor will specifically note items that have been corrected during the on-site assessment along with any recommendations for other action(s). The process for resolving nonconformities identified during the on-site assessment is documented in NIST Handbook 150. Any disagreements between the laboratory and an assessor may be referred to NVLAP headquarters for resolution.

3.3.7 The laboratory shall address all nonconformities and provide, within 30 days from the date of the on-site assessment, a response to NVLAP headquarters.

3.3.8 The laboratory shall review all comments for potential improvements in the testing of radiation detection instruments used for homeland security.

3.4 Proficiency testing

3.4.1 Conducting proficiency testing

3.4.1.1 NVLAP will require proficiency testing rounds as needed to evaluate a laboratory's proficiency.

3.4.1.2 Laboratories shall participate in proficiency testing when NVLAP announces plans to conduct a proficiency test.

3.4.2 Analyzing and reporting proficiency data

The laboratory shall evaluate the proficiency testing results, identify all outliers and follow the requirements of NIST Handbook 150 for the control of nonconforming work.

3.4.3 Proficiency testing nonconformities

The laboratory shall correct the problems that led to the poor performance in proficiency testing. The laboratory's accreditation may be suspended if the proficiency testing results indicate continued poor or unsatisfactory performance on consecutive proficiency testing rounds.

4 Management requirements for accreditation

4.1 Organization

There are no requirements additional to those set forth in NIST Handbook 150.

4.2 Management system

4.2.1 The requirements for a management system are contained in NIST Handbook 150, *NVLAP Procedures and General Requirements*.

4.2.2 The controlled version of the laboratory management system documentation may be paper-based or computer-based. Version control shall be maintained in either case.

4.2.3 If the laboratory uses a computer-based documentation system, the laboratory should consider the ease of usability by the staff. The laboratory shall ensure that the requirements of NIST Handbook 150 are met so that staff is knowledgeable about the online documentation system and can readily retrieve appropriate information.

4.2.4 The laboratory shall create a cross-reference document allowing the laboratory and a NVLAP assessor to verify that all requirements of clauses 4 and 5 and annexes A and B of NIST Handbook 150 and the corresponding NIST Handbook 150-23 are addressed in the management system documentation.

4.2.5 The laboratory shall develop and implement procedures covering all the technical requirements of this handbook.

4.2.6 The most recent editions of the documents listed in 1.4 shall be available as references in maintaining the management system.

4.2.7 A general reference text on statistics shall be available in the laboratory.

4.2.8 The laboratory shall have copies of applicable referenced standards, practices and procedures.

4.2.9 In addition to the information specified in NIST Handbook 150, the quality manual and/or supporting management procedures shall include the following:

- a) laboratory's facilities and scope of services offered;
- b) equipment inventory including radiation sources used for testing;
- c) radiation detection instrument models and design specifications for those instruments used in support of type testing, including maintenance and calibration practices;
- d) environmental chambers, thermometers and humidity measurement instrumentation, including maintenance and calibration practices;
- e) procedures for handling and storing sensitive components and materials;
- f) electromagnetic testing instrumentation, including maintenance and calibration practices;

- g) dust and water spray testing instrumentation, including maintenance and calibration practices;
- h) vibration and mechanical shock testing instrumentation, including maintenance and calibration practices;
- i) assembly/disassembly techniques for all portal monitors to be tested, if applicable;
- j) identification and tracking of radiation detection instruments received;
- k) handling, control and shipping of radiation detection instruments used in proficiency testing;
- l) actions concerning damaged radiation detection instruments received in shipping;
- m) instructions to operate all radiation detection instruments, including any operational checks;
- n) data handling and reporting that includes report data file templates following the format given in the testing and evaluation protocols for each type of instrument;
- o) actions when test data indicate a possible problem exists;
- p) policy for utilizing subcontractors.

4.3 Document control

There are no requirements additional to those set forth in NIST Handbook 150.

4.4 Review of requests, tenders and contracts

There are no requirements additional to those set forth in NIST Handbook 150.

4.5 Subcontracting of tests and calibrations

There are no requirements additional to those set forth in NIST Handbook 150.

4.6 Purchasing services and supplies

There are no requirements additional to those set forth in NIST Handbook 150.

4.7 Service to the customer

There are no requirements additional to those set forth in NIST Handbook 150.

4.8 Complaints

There are no requirements additional to those set forth in NIST Handbook 150.

4.9 Control of nonconforming testing and/or calibration work

There are no requirements additional to those set forth in NIST Handbook 150.

4.10 Improvement

There are no requirements additional to those set forth in NIST Handbook 150.

4.11 Corrective action

There are no requirements additional to those set forth in NIST Handbook 150.

4.12 Preventive action

There are no requirements additional to those set forth in NIST Handbook 150.

4.13 Control of records

Records shall be maintained for at least three years.

4.14 Internal audits

4.14.1 The most recent internal audit report shall be available for review during NVLAP on-site assessments.

4.14.2 Previous internal audit reports for the past three years, if applicable, shall be available for review if requested by the NVLAP assessor.

4.14.3 The internal audit shall cover compliance with NVLAP, laboratory management system, regulatory, and contractual requirements.

4.14.4 The laboratory shall perform a complete internal audit of its management system prior to the first on-site assessment.

4.15 Management reviews

4.15.1 Periodic reviews of the management system shall reflect adherence to NVLAP requirements and the laboratory's quality objectives.

4.15.2 The periodic management system reviews shall reflect positive aspects of the management system as well as nonconformities.

4.15.3 The most recent management review report shall be available for review during NVLAP on-site assessments.

4.15.4 Previous management review reports for the past three years, if applicable, shall be available for review if requested by the NVLAP assessor.

4.15.5 The laboratory shall perform at least one complete management review prior to the first on-site assessment.

5 Technical requirements for accreditation

5.1 General

The quality manual shall contain, or refer to, documentation that describes and details the laboratory's implementation of procedures covering all of the technical requirements in NIST Handbook 150 and this handbook.

5.2 Personnel

5.2.1 The laboratory shall maintain a list of personnel designated to fulfill NVLAP requirements including Laboratory Director, Technical Director, Team Leaders, NVLAP Authorized Representative, and NVLAP Approved Signatories.

5.2.2 The Technical Director should be a professional experienced in radiation detection instrumentation and be familiar with the radiation detection instrumentation currently utilized.

5.2.3 When key personnel are added to the staff, the notification of changes shall include a current resume for each new staff member.

5.2.4 Laboratories shall document the required qualifications for each staff position. The staff information may be kept in the official personnel folders or in separate folders that contain only the information that NVLAP assessors need to review.

5.2.5 The training program shall be updated when procedures change.

5.2.6 Staff members shall be retrained when procedures change, or when the individuals are assigned new responsibilities. Each staff member may receive training for assigned duties through on-the-job training, formal classroom study, attendance at conferences, or another appropriate mechanism.

5.2.7 Training materials that are maintained within the laboratory shall be kept up-to-date.

5.2.8 For each staff member, the staff member's immediate supervisor, or a designee appointed by the Laboratory Director, shall conduct an annual assessment and observation of performance.

5.2.9 Individuals hired to perform testing activities are sometimes referred to as *subcontractors*. NVLAP does not make a distinction between full-time laboratory employees and individuals hired on a contract. NVLAP requires that the laboratory maintain responsibility for and control of any work performed within its scope of accreditation. The laboratory shall ensure all individuals performing radiation detection instrument testing activities satisfy all NVLAP requirements, irrespective of the means

by which individuals are compensated (e.g., the laboratory must ensure all test personnel receive proper training and are subject to annual performance reviews, etc.).

5.3 Accommodation and environmental conditions

There are no requirements additional to those set forth in NIST Handbook 150.

5.4 Test and calibration methods and method validation

5.4.1 A laboratory may be accredited to perform standard test methods in their entirety or to perform only certain sections in the test method.

5.4.2 The laboratory shall have written procedures for laboratory personnel to follow when conducting tests. If determined suitable by NVLAP, the laboratory may use the specific standard test method as the only written procedures.

5.4.3 The procedures shall address any information not specifically contained in the standard method and any deviations used by the laboratory.

5.4.4 The procedures shall include equipment operation, calibration checks, and quality control checks.

5.4.5 The laboratory shall develop validation methods to ensure that the test fields and relevant quantities used for equipment testing are within acceptable tolerances. Acceptable tolerances for measurable quantities are set to $\pm 5\%$ unless otherwise specified by the ANSI standards and their associated test and evaluation protocols.

5.4.6 The laboratory shall document uncertainty of the radiation fields used for testing and the traceability to NIST or equivalent foreign national metrology standards.

5.5 Equipment

A laboratory and/or subcontractor shall have adequate facilities and equipment to perform the radiation detection instrumentation tests for which capability is claimed. Adequate facilities and equipment shall include the following:

- a) sufficient space to perform the validation tests;
- b) proper shielding of areas from unwanted radiation;
- c) necessary environmental chambers for conducting environmental tests;
- d) radiation sources that are NIST-traceable or traceable to a national metrology institute;
- e) safety systems;
- f) properly calibrated test equipment;

- g) electromagnetic and mechanical test equipment for conducting electromagnetic and mechanical tests.

5.6 Measurement traceability

5.6.1 The laboratory shall determine equipment calibration intervals based on the equipment's frequency of use and the environment in which it is used, in accordance with standard test methods.

5.6.2 The laboratory shall provide proof that the calibration intervals used by the laboratory are sufficient.

5.6.3 Proper performance of the testing equipment shall be periodically verified.

5.6.4 The radiation sources and reference standards used and the environmental conditions at the time of calibration shall be documented for all calibrations.

5.6.5 The radiation sources and reference standards used and the environmental chamber conditions at the time of the test shall be documented for all type tests.

5.6.6 Calibration records, type testing records, and evidence of the traceability of the radiation sources and reference standards used shall be made available for inspection during the on-site visit.

5.6.7 Calibration records for equipment used for measurements and evaluation of radiation detection instruments shall include the following:

- a) notation of all equipment variables requiring calibration or verification;
- b) range of calibration/verification;
- c) resolution of the instrument and its allowable uncertainty;
- d) calibration/verification date and schedule;
- e) identity of the laboratory individual or external service responsible for calibration;
- f) traceability of radiation sources and reference standards.

5.7 Sampling

There are no requirements additional to those set forth in NIST Handbook 150.

5.8 Handling of test and calibration items

There are no requirements additional to those set forth in NIST Handbook 150.

5.9 Assuring the quality of test and calibration results

5.9.1 The categories for performance testing and the associated tolerance limits for both type testing and proficiency testing are based on the requirements of radiation detector performance standards, such as ANSI/IEEE N42.32, N42.33, N42.34, N42.35, N42.38, and N42.43 and their corresponding testing and evaluation protocols.

5.9.2 The ANSI/IEEE N42 series of standards and their respective testing and evaluation protocols specify radiation sources to be used in the radiological detection tests and radionuclide identification tests. The radiation sources used by the testing laboratories shall be traceable to the NIST or to an equivalent national metrology institute, as a requirement for use in the type testing and proficiency testing program.

5.9.3 The laboratory shall have procedures for verification and validation of software used to acquire data from the instruments used for testing.

5.10 Reporting the results

The laboratory shall report the test results in accordance to the latest reporting format provided in the test and evaluation protocols associated with the individual standards.

6 Additional requirements

There are no additional requirements beyond NIST Handbook 150 and its associated normative annexes, and any other normative references previously cited in this handbook.